EXHIBIT A

STATE OF INDIANA	)	ST. JOSEPH SUPERIOR COURT
	) SS.	
ST. JOSEPH COUNTY	)	
IN RE: STEROID INJECTION	)	CAUSE NO. 71D06-1405-CT-136
LITIGATION AGAINST	)	CAUSE NO. 71D06-1406-CT-181
SOUTH BEND CLINIC, LLP	)	CAUSE NO. 71D06-1406-CT-211
		CAUSE NO. 71D07-1407-CT-257
		CAUSE NO. 71D06-1409-CT-320
		CAUSE NO. 71D06-1408-CT-300

ORDER

The following cases have been consolidated for purposes of pre-trial discovery and preliminary motions. One of the reasons for consolidation was to allow the Indiana Department of Insurance (IDOI) as Administrator for the Indiana Patient's Compensation Fund (PCF) to avoid appearances in multiple cases in multiple courts but rather argue their position in a consolidated hearing. All St. Joseph County cases have been consolidated before this court. A similar consolidation of cases has occurred in Elkhart County before the Honorable Evan S. Roberts, Elkhart Superior Court, No. 1.

Below is a list of the consolidated cases in the St. Joseph County Superior Court:

71D06-1405-CT-000136
Terri Rethlake v. ABC Clinic

71D06-1406-CT-000181
Deborah Barnes, et al v. The South Bend Clinic LLP

71D06-1406-CT-000211
Charles Jones, et al v. South Bend Clinic LLP, et al

71D07-1407-CT-000257
Joan Rothballer v. South Bend, Clinic LLP

71D06-1409-CT-000320
Laura Wyza, et al v. South Bend Clinic LLP

71D06-1408-CT-000300
John Reed, et al v. ABC Clinic

PROCEDURAL BACKGROUND

On May 19, 2015, Defendant South Bend Clinic LLP (SBC) filed a Consolidated Motion to Dismiss. The SBC asked the court to dismiss plaintiffs' complaints. The complaints are characterized as alleging negligence arising out of the health care provided to them by the SBC. SBC argues that the complaints are not in compliance with the Medical Malpractice Act (MMA) as to limitation to an anonymous defendant and failure to follow the medical review panel process. At the hearing on the consolidated motion, the SBC counsel and counsel for plaintiffs agreed that if the motion is granted, the complaints will be revised to provide only anonymous recognition of the defendant clinic, and stayed until compliance with the MMA procedures, I. C. §34-18-8-4.

Both Defendant SBC and the plaintiffs agree that the cases are under the MMA which require presentation to medical review panels. The only party that opposes this motion to dismiss is the Indiana Department of Insurance (IDOI) as Administrator for the Indiana Patient's Compensation Fund (PCF).

The PCF claims that the underlying complaints are not based on the rendering of medical or health related services and therefore asserts these claims do not fall under the MMA.

PRELIMINARY DETERMINATIONS OF FACT

1. This proceeding arises as a result of an outbreak of fungal meningitis, fungal infections and other related complications that affected individuals in at least twenty states and caused, at a minimum, 64 deaths. The outbreak resulted in deaths and injuries to Hoosiers and

Michigan residents who received treatment in Indiana. Indiana and Michigan were hit particularly hard. The CDC identified 93 cases of Hoosiers diagnosed with fungal infections linked to contaminated epidural injections, with 11 of those resulting in death. Michigan was the hardest hit state, with a case count of 264, and 11 of those resulting in death. There are many more individuals who received a contaminated injection who suffered injury from the injection, but who have not been identified as a "case" by the CDC. Barnes Amended Complaint for Damages, paras. 1, 111 (hereafter referred to as "Complt").

2. Plaintiffs are individuals or their representatives who suffered injury or death as a direct result of being administered one or more contaminated epidural injections. Each plaintiff has alleged that he or she underwent an epidural steroid injection under the care of SBC as follows:

Sharon Shafer on August 30, 2012 (Exhibit C1, ¶ 4);

Kristi Oblinger on September 10, 2012 (Exhibit C2, ¶ 4);

Yolanda Ivory on September 6, 2012 (Exhibit C3, ¶ 4);

Deborah Barnes on August 20, 2012 and September 13, 2012 (Exhibit C4, ¶ 4);

Pearl Stokes on September 20, 2012 (Exhibit C5, ¶ 4);

Staci VanSchoiack on September 20, 2012 (Exhibit C6, ¶ 4);

Laura Wyza on September 6, 2012 (Exhibit C7, ¶ 4);

Terri Rethlake on September 20, 2012 (Exhibit C8, ¶ 4);

Joan Rothballer on July 26, 2012 and September 13, 2012 (Exhibit C9, ¶ 4);

John Reed on August 27, 2012 (Exhibit C10, ¶¶ 4); and

Terri Jones on March 15, 2012 and July 2, 2012 (Exhibit C11, ¶¶ 4, 5, and 6).

Plaintiffs also include the spouses of certain individuals who received such contaminated injections. See Complt. paras. 4, 5. Those plaintiffs who received services from SBC sought treatment of back pain and related spinal conditions. Such services included physical therapy, epidural injections, pain medications and surgery. Id. para. 181. Each of the patient-plaintiffs was a "patient", as defined by the MMA, of SBC when they received their epidural steroid injections. See I.C. 4-18-2-22.

3. Defendant SBC is a qualified health care provider under MMA which was and is engaged in the business of providing health care and selling medical related products. Id. paras. 6-7. The plaintiffs' complaints, filed before the St. Joseph Circuit and Superior Courts, each allege a claim arising out of the patient-health care provider relationship.

4. The intervening party in this litigation is the Patient's Compensation Fund (hereafter referred to as "PCF"). Under the provisions of the Indiana Medical Malpractice Act (hereafter referred to as "MMA"), the PCF is responsible for payment of a plaintiff's claim which is determined by trial or through settlement to be a recoverable claim and where the health care provider in question, through its insurer, had paid as required under the MMA. See I.C. 34-18-14-3.

5. Plaintiffs' proposed complaints filed with the IDOI (SBC's Exhibits C1 through C11) pleaded factual allegations about the patient-health care provider relationship each plaintiff had with SBC. Each proposed complaint alleges that the plaintiff was "injected with a contaminated epidural product" when he or she was treated at SBC. (See SBC's Exhibits C1 through C11).

6. Plaintiffs allege in 1998, Gregory Conigliaro and Barry Cadden co-founded the New England Compounding Pharmacy, Inc., known as New England Compounding Center ("NECC"), in Massachusetts. Other members of the Conigliaro and Cadden families came to be

involved with NECC either as owners, officers or employees. Complt. paras. 14-19. Other related entities to NECC were established by the Conigliaros and Barry Cadden, including Medical Sales Management, Inc., Ameridose, LLC and Alaunus Pharmaceutical, LLC in the State of Massachusetts. Id. paras. 20-26.

7. Plaintiffs allege NECC operated as a compounding pharmacy. Plaintiffs assert that compounding pharmacies are prohibited from mass production of pharmaceutical products but may only produce products that have a particular demand need, such as a drug for a patient who is allergic to an ingredient in a mass produced, FDA regulated product or a pharmaceutical product that is no longer manufactured. Id. paras. 28-32.

8. Plaintiffs allege SBC purchased preservative-free methylprednisolone acetate ("MPA") from NECC. MPA is a steroidal product that can be injected into the area of the lumbar spine to provide pain relief to individuals who suffer with low back pain and related symptoms. Id. paras. 2, 3, 151, 154, 181.

9. Plaintiffs allege there are particular safety and product quality risks associated with purchasing pharmaceuticals from a compounding pharmacy. Id. paras. 33-40. The risk is heightened for those pharmaceutical products that are made without preservatives, due to the increased risk of their being or becoming contaminated. Id. paras. 140-146.

10. Plaintiffs allege an outbreak of fungal meningitis, lumbar fungal infections and related injuries and complications arose in September, 2012. The Center for Disease Control ("CDC") was notified by the Tennessee Department of Health of a patient who developed fungal meningitis after receiving an epidural steroidal injection. Id. paras. 41-49. Additional patients developing fungal meningitis were next identified in Massachusetts and the outbreak continued spreading to 19 states, including Indiana and Michigan. The outbreak was the result of patients

receiving one or more contaminated injections from three different lots of MPA compounded by NECC (lot numbers 05212012@68, 06292012@29 and 08102012@51) or from another contaminated NECC medication. Id. paras. 50-57.

11. Plaintiffs allege The Food and Drug Administration ("FDA") and the Massachusetts Department of Public Health ("MDPH") began investigating NECC, along with the involvement of other state and federal agencies. On September 26, 2012, NECC recalled the three lots of MPA found to be contaminated. The suspected lots contained 17,676 dosage vials. Of this number, more than 14,000 were used for injections. Only about 3,000 doses were returned through the recall process. Id. paras. 51-57.

12. Plaintiffs allege the investigation of NECC revealed black particulate matter in sealed, returned vials of MPA. Id. paras. 64-66. Vials also contained a greenish black foreign matter and others a white filamentous material. Sterility analysis later confirmed the presence of "viable microbial growth" in all of the 50 vials tested. Id. paras. 75-88.

13. Plaintiffs allege, in addition to the foregoing, the MDPH in its investigation found the following:

a. NECC had distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license.

b. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

c. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

d. The clean rooms used to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.

e. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation within the sterile compounding area, were not thoroughly cleaned pursuant to U.S. Pharmacopeial Convention ("USP") 797 or pursuant to NECC standard operating procedures. Residual powder was visually observed, which could lead to contamination of compounded medications.

f. "Tacky mats" used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris, in violation of USP 797.

g. A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.

The FDA also conducted an investigation of NECC and found even more detailed specific violations. See Complt. paras. 64-74.

14. Plaintiffs allege NECC was supposed to have undertaken sterility testing before selling and distributing its preservative-free MPA products to local clinics. It failed to do so, including vials sold to SBC. NECC distributed two of the recalled lots of preservative-free MPA before receiving its sterility testing. Lot 06292012@26 was prepared on June 29, 2012, with shipments made shortly thereafter. Final sterility testing, however, was not completed until July 17, 2012. In addition, two shipments of product were made before the final sterility test results were received. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. At least eleven shipments of product were sent out before the final sterility test results were received. Id. para. 64-66.

15. The medical staff of SBC made the determination to use preservative-free MPA in undertaking its lumbar epidural injections. See Deposition of Kathryn Park, p. 15, ln. 17-24; Deposition of Margaret Bowsman, p. 13, ln. 5-11.

16. The decision of SBC to use NECC as its supplier of preservative-free MPA was made by its medical staff. Park Dep. p. 22, ln. 9 – p. 23, ln. 14; Bowsman Dep. p. 8, ln. 1-18.

17. The handling of orders of non-preservative-free MPA and the overall management of the supplier relationship with NECC was undertaken by the nursing staff of SBC. Park Dep. p. 23, ln. 17-25; Bowsman Dep. p. 7, ln. 15-25; p. 20, ln. 2 – p. 22, ln. 23.

18. Plaintiffs contend SBC was negligent in a number of respects with respect to its purchasing practices and supplier dealings with NECC. These allegations include the following:

a. SBC was negligent in dealing with NECC, as the latter was operating illegally under its license issued by the Massachusetts Board of Registration and Pharmacy. NECC was not operating as a true compounding pharmacy, but as a bulk pharmaceutical producer, which is not sanctioned by state compounding pharmacy laws;

b. SBC was negligent in that it should have known that NECC was operating as a bulk, mass pharmaceutical manufacturer, and as such, it could only lawfully operate pursuant to FDA authorization and regulation;

c. SBC did not provide individual signed prescriptions for each of its patients for each dosage of the preservative-free MPA from NECC. Such individual signed prescriptions were required not only under the laws of the State of Massachusetts, but also under the laws of the State of Indiana. Instead, SBC used mass produced order forms and a single doctor's signature which was photocopied repeatedly on such bulk order forms;

d. Apart from not being properly licensed or authorized by either the State of Massachusetts or the FDA, NECC was also not accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organization. Id. para. 146.

e. SBC also failed to perform the due diligence steps recommended by the national group of health system pharmacists, the American Society of Health-Systems Pharmacists ("ASHP").

Complt. paras. 112-163.

19. Plaintiffs have also asserted claims of negligent misrepresentation and omission. Plaintiffs allege that SBC "misrepresented and/or omitted material facts about the quality and safety of the epidural products to the public, consumers and Plaintiffs, among others." Plaintiffs further allege that SBC's misrepresentations "included the representation that the epidural products it used were safe for the purposes for which they were intended." Plaintiffs contend such representations were false and that plaintiffs were not aware of such falsity and relied such representations to their detriment. Complt. paras. 166-172.

ANALYSIS

20. To determine the applicability of the MMA, the relevant provisions should be first examined. The MMA defines malpractice as "a tort or breach of contract based on health care or professional services that were provided, or that should have been provided, by a health care provider, to a patient." I. C. 34-18-2-18. Health care is "an act or treatment performed or furnished, or that should have been performed or furnished, by a health care provider for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement." I. C. 34-18-2-13. A "patient" is "an individual who receives or should have received health care from a health

care provider, under a contract, express or implied, and includes a person having a claim of any kind, whether derivative or otherwise, as a result of alleged malpractice on the part of a health care provider." I. C. 34-18-2-22.

21. The MMA covers "curative or salutary conduct of a health care provider acting within his or her professional capacity". Collins v. Thakkar, 552 N.E.2d 507, 510 (Ind. Ct. App. 1990), trans. denied. The MMA does not apply to conduct unrelated to "the promotion of a patient's health or the provider's exercise of professional expertise, skill, or judgment." Howard Reg'l Health Sys. v. Gordon, 952 N.E.2d 182, 185 (Ind. 2011); Doe by Roe, 652 N.E.2d 101, 103 (Ind. Ct. App. 1995), trans. dismissed.

22. Plaintiffs are alleging that the process used in the acquisition of MPA was undertaken negligently. Plaintiffs contend it is the process of selecting NECC as a supplier and then managing and overseeing that supplier relationship which plaintiffs contend was done negligently and improperly by SBC.

23. With reference to the term "health care" under the MMA, the "act" of selecting NECC as a supplier and the ongoing "acts" of acquiring product from NECC and managing that supplier relationship were "performed" or "should have been performed" by "a health care provider," here SBC. These "acts" were undertaken by SBC "for…or on behalf of" its "patients." These "acts" were undertaken as part of the patient's "medical care or treatment." Such "acts" of selecting a pharmaceutical supplier and managing that drug supplier relationship fall squarely within the definition of "health care" as defined by and covered under the MMA. I. C. 34-18-2-13. Dr. Park's decision to procure MPA from NECC to administer to her patients during the course of their treatment meets the express definition of health care under the MMA. An act, the procurement of MPA from NECC, was performed by a health care provider, Dr.

Park, on behalf of her patients, the plaintiffs, during their medical care and treatment. Thus, Dr. Park's procurement of MPA from NECC for her patients is expressly included in the definition of health care, I.C. 34-18-2-13, which is expressly included within the definition of malpractice, I.C., 34-18-2-18, covered by the MMA.

24. In determining the applicability of the MMA, Indiana courts also look to "the design and procedures of the Act, especially submitting the complaint to a medical review panel for the purpose of expressing an expert opinion." H.D. v. BHC Meadows Hosp., Inc., 884 N.E.2d 849 (Ind. Ct. App. 2008). See Winona Memorial Foundation, of Indianapolis v. Lomax, 465 N.E.2d 731, 733 (Ind. Ct. App. 1984), reh'g denied. In Collins v. Thakkar, 552 N.E.2d 507, 510-511 (Ind. Ct. App. 1990), the court further explained this aspect of the MMA:

> The legislature's establishment of a medical review panel, the sole purpose of which is to provide an expert determination on the question of whether a provider complied with the appropriate standard of care, suggests that the scope of the Act is likewise confined to actions premised upon the exercise of professional judgment.

25. The issues involving the claim of negligence of SBC in selecting NECC as a supplier and its ongoing use and management of NECC as a supplier are not issues within the knowledge of the typical man or woman. Rather, specific knowledge regarding the pharmaceutical industry and pharmaceutical practices and the practice of medicine will be required. These include:

1. Requirements for patient specific prescriptions, each signed by an authorized practitioner and related requirements pertaining to patient specific prescriptions;
2. Applicable state licensing requirements, and operating within such licensing authority;
3. Issues pertaining to FDA regulation of pharmaceutical manufacturers;

4. Proper operating procedures to be used by compounding pharmacies, including use and standards applicable to clean rooms where the drugs are compounded and use of equipment within such rooms;

5. Standards applicable to a purchaser of pharmaceutical products, specifically due diligence steps that should be taken when selecting a compounding pharmacy and then in the ongoing management of the supplier relationship with a compounding pharmacy. This would include site inspections, evaluation of standard operating procedures and quality control reports, supplier accreditation standards, to name a few;

6. Also to be considered will be the standards established by overseeing and regulating pharmaceutical bodies, including ASHP, USP and NIOSH. These will include applicable standards involving the selection of a pharmaceutical supplier, the purchasing of pharmaceutical products and the ongoing management of that supplier relationship.

26. Expertise as to such pharmaceutical/medical issues will be required to evaluate plaintiffs' claims against SBC. The MMA requires that there be a review panel, comprised of members with such pharmaceutical/medical expertise, to evaluate plaintiffs' claims. The need for such expertise leads to the conclusion that the MMA is applicable to plaintiffs' claims.

27. In addition, a dispositive case is St. Mary Medical Center v. Casko, 693 N.E.2d 312 (Ind. App. 1994), which involved a patient who received a pacemaker while a patient at St. Mary and later died due to an alleged defect with the pacemaker. His estate brought claims against the manufacturer of the pacemaker and against St. Mary, which sold the pacemaker to Mr. Casko as part of its implant surgery and follow-up care. The court concluded Casko's claim did not fall

within the scope of Indiana's Product Liability Act, relying upon the definition of the term "product." See I. C. 31-1-1.5-2. "Product" is defined as an "item or good . . . conveyed by a seller to another party. It does not apply to a transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product." Id. The court went on to conclude that plaintiff's claim fell within the scope of the MMA. Relying upon a prior precedent and noting that the acts of acquiring and providing the pacemaker were "incidental" to the provision of the medical care [the surgical procedure to implant the pacemaker], the MMA was found applicable to Casko's claim. 639 N.E.2d at 314, 315. See Dove by Dove v. Ruff, 558 N.E.2d 836 (Ind. App. 1990), trans. denied ("By its nature, the practice of medicine is primarily a service, but there are times when goods are provided to patients incidental to the delivery of health care services. The providing of such goods does not normally remove the health care professional from the protection of the Malpractice Act.").

28. In this case, plaintiffs came to SBC for the primary purpose of obtaining services for treatment for their back pain. Such services range from undertaking back surgery, to receiving epidural steroidal injections, to receiving physical therapy, to receiving a prescription for pain medication. For such services involving provision of an epidural injection, the steroidal product itself, here MPA, was incidental to the delivery of the health care services in question - the treatment of back pain. As was the case in Casko and Dove, "providing such goods does not normally remove the health care professional from the protection of the Malpractice Act." Consequently, the claims by plaintiffs here predominantly involve the "act" of "health care" rendering the MMA applicable.

29. In Section III of its Brief in Support of Motion for Summary Judgment, the PCF asserts that a determination that the MMA is applicable to the claims at issue would "jeopardize"

health care in Indiana. PCF Memorandum p. 14-17. The PCF acknowledges the controlling provisions of the MMA regarding its potential liability on plaintiffs' claims.

30. Under the MMA, the total recovery in a medical malpractice action is limited to $1,250,000 per injury or death. I. C. 34-18-4-3. The MMA caps a health care provider's malpractice liability at $250,000 per occurrence if the provider maintains sufficient insurance and pays the required surcharge to the PCF. I. C. 34-18-3-1, 34-18-14-3(b). In addition, subject to additional statutory requirements, "[i]f an annual aggregate for a health care provider qualified under this article has been paid by or on behalf of the health care provider, all amounts that may subsequently become due and payable to a claimant arising out of an act of malpractice of the health care provider occurring during the year in which the annual aggregate was exhausted shall be paid from the [PCF]." I. C. 34-18-6-6. PCF Memorandum p. 14, 15. The PCF then argues that these provisions were not intended to apply to plaintiffs' claims, which number more than 100, as they involve a defective medical product used during the course of providing health care to the plaintiffs.

31. Indiana courts have recognized that they may not distort our English "language to 'rewrite' ...[a] statute." See Scott v. Irmeger, 859 N.E.2d 1238, 1243 (Ind. App. 2007). Indeed, as further explained in "Myers v. State, 714 N.E.2d 276, 284 (Ind. Ct. App. 1999): "We may not ignore the clear language of a statute and 'in effect rewrite a statute in order to render it consistent with . . . [another's (here the PCF's)] view of sound public policy.' (quoting Robinson v. Monroe County, 663 N.E.2d 196, 198 (Ind. Ct. App. 1996)), trans. denied. Moreover, the "separation of powers [of state government] prevents a court from effectively rewriting a statute to save it from constitutional [or other] infirmity." Indiana Wholesale Wine & Liquor Co. v. State ex rel. Indiana Alcoholic Bev. Comm'n, 695 N.E.2d 99, 108, fn 21 (Ind. 1998); Grody v.

State, 257 Ind. 651, 659-60, 278 N.E.2d 280, 285 (1972) (quoting Aptheker v. Secretary of State, 378 U.S. 500, 515, 12 L. Ed. 2d 992, 84 S. Ct. 1659 (1964)). The assertion of the PCF runs contrary to these legal precepts. It asks this court to rewrite or ignore the plain language of the MMA to render it inapplicable to plaintiffs' claims. This is something that this court cannot properly do.

32. Indiana's MMA applies to all malpractice claims, whether it is a claim involving a single incident, a single patient and a single provider, or many claims by many persons against a single provider. The MMA has no provision for treating such single claim incidents and multiple claim incidents differently. Moreover, claims of alleged negligence in the selection of a medical product supplier and negligence in the management of that supplier relationship fall within the definition of "health care" under the MMA, as concluded earlier in this court's conclusions of law. The entreaty by the PCF to this court to rewrite the MMA must be rejected.

33. The duty to obtain informed consent "arises from the relationship between the doctor and patient, and is imposed as a matter of law, as are most legal duties." Culbertson v. Mernitz, 602 N.E.2d 98, 101 (Ind. 1992) (citation and quotation marks omitted). It is well-settled in Indiana law that, "[i]n the course of rendering professional services to a patient, a physician's acts of negligence, including acts which constitute a breach of the duties to disclose information and obtain informed consent, are malpractice." Boruff v. Jesseph, 576 N.E.2d 1297, 1299 (Ind. App. 1991); see I.C. 16-9.5-1-1(h); Kranda v. Houser-Norberg Medical Corp., 419 N.E.2d 1024, 1037 (Ind. 1981) reh'g denied, 424 N.E.2d 1064, appeal dismissed, (1982), 459 U.S. 802, 103 S.Ct. 23, 74 L.Ed.2d 39. Informed consent actions are based upon a breach of the physician's duty to "make reasonable disclosure of material facts relevant to the patient's decisions about treatment. . . ." Collins, 552 N.E.2d at 511, fn. 6.

34. Plaintiffs' negligent misrepresentation claims are, in substance, informed consent claims. Such claims are a type of medical malpractice claim. Such informed consent claims also bring plaintiffs' complaint within the scope of the MMA.

35. The common allegation in the complaints is that the SBC failed to use appropriate, necessary and reasonable due diligence in the acquisition of the NECC preservative-free product (MPA).

36. The court has been presented with an allegation of the plaintiffs that the process for obtaining a medical compound is different from the process of obtaining other drugs from a pharmaceutical manufacturer.

37. Paragraph 27 of the Barnes complaint provides: "According to the FDA, traditional pharmacy compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. Traditional compounding is used to prepare a particular medication or formulation that is not mass-produced by an FDA licensed and approved pharmaceutical manufacturer, such as a drug for a patient who is allergic to an ingredient in a mass-produced product; a particular drug, cream or similar (sic) that is not mass-produced or diluted dosages for children."

38. It is important to understand that the prescription for a normal mass-produced medicine goes to a local pharmacy for simple dispensing from inventory purchased from the manufacturer. The prescription for a normal medication is never sent to the manufacturer prior to the creation of the medicine. In contrast, for a compounding pharmacy, the plaintiffs have alleged, and it must be taken as true for this motion to dismiss, that the procedure for a compounding pharmacy is that the doctor's prescription for the creation of the medicine must be

received by the compounding pharmacy prior to the creation of the specific medicine. This obligation of direct relationship between the doctor and the compounding pharmacist coupled with the understanding that a preservative-free medicine is inherently more risky than a preservative based medicine, at least in terms of infection by biological agents which may grow in a preservative-free solution, presents a unique and limited circumstance which requires this court to conclude that the SBC did have a duty to use its professional judgment, as exercised through its doctors and nurses as agents for the clinic, to fulfill the due diligence of considering whether the creator of that specialized medicine was a competent and safe supplier for its patients.

39. The Indiana Department of Insurance, Patient's Compensation Fund, ("PCF") in its reply to SBC's Motion to Dismiss states on the bottom on page 2 and the top of page 3 that "a selection of the vendor and oversight of the supplier relationship for every product or device used in patient treatment from cotton balls, to surgical instruments, to CT scanners" is not health care under the Medical Malpractice Act.

40. The differences from the example cited by the PCF and the facts of this case are that a prescription is not required to buy cotton balls or surgical instruments or CT scanners. However, to buy a specifically compounded drug for a specific patient, a prescription is necessary. In addition, the medical decision to use an injected liquid, which does not have preservatives, is a medical judgment. It is obvious to the lay person that eating food that has been stored for months and which is not preserved is a risky proposition. There are preservatives in food and there are preservatives in medicine which may have some side effects; however, they protect the food sources of human beings and the medicines of human beings from infectious agents. Lay persons must use a lay judgment as to food, but our society relies upon expert

medical training and licensing to decide what should be injected into the spine. Dr. Park made a medical decision, and the SBC carried out Dr. Park's decision in purchasing from the NECC a preservative-free injectable medication. Dr. Park and her clinic, the SBC, made a medical judgment that it was worth the risk to benefit patients by reducing reactions to preservatives even though that risk included a higher potential for unclean solution to be injected into patients. This is a much more specific medical decision than purchasing cotton balls, surgical instruments, CT scanners, or attaching lighting fixtures to a wall. The selection and purchase of MPA is curative or salutary conduct of a health care provider. The authorization by a doctor and ordering of the MPA by a nurse and administrative personnel of the SBC is not demonstrably unrelated to promotion of a patient's health and is part of professional judgment. Howard Reg. Health Sys. v. Gordon, 952 N.E.2d 182 (Ind 2011). The PCF has cited the case of Winona Mem'l Hosp. v. Kuester 737 N.E.2d 824 (Ind. Ct. of App. 2000), in paragraphs 13 and 14 of their proposed findings. The Kuester case leads this court to the conclusion that this case supports an expansive reading of the MMA. The Court of Appeals in Kuester quoted an earlier case as follows:

> Viewed from the historical perspective we believe the conclusion is inescapable that our General Assembly intended that all actions the underlying basis for which is alleged medical malpractice are subject to the act.

and further stated:

> Further, we subscribed to the reasoning that, the Act applies to conduct, curative or salutary in nature, by a health care provider acting in his or her professional capacity and is designed to exclude only conduct which is unrelated to the promotion of the patient's health or the provider's exercise of the professional expertise skill or judgment. . . . we hold that the credentialing of a (doctor) is directly related to the provision for health care and is therefore not excluded from the Act.

737 N.E.2d at 828

Similarly, the procurement of the patient-specific, prescription-created, non-preserved compound is directly related to the provision of health care.

41. Due diligence is a variable obligation depending upon the circumstances of each case. If a drug, such as aspirin, has been safely used for decades, then the prescription of an aspirin compound would have a very low due diligence requirement as to the supplier of the aspirin. If a prescription medication is produced by a well-known pharmaceutical company and has been patented and has been produced for years with successful treatment of patients and a good safety record, the due diligence of a doctor and medical provider is low. However, when the facts are similar to this case where a doctor made a decision to use preservative-free medicine and a prescription was required for each specific compound for each specific patient, and also a long history of safe production of this specific compound by reputable pharmaceutical manufacturers was absent, then the due diligence requirement should be higher on the health care provider. The medical professional must exercise judgment in determining whether the benefits outweigh the risks, which is medical judgment. That is judgment that is not subject to ordinary lay person comprehension. That is also judgment for which a doctor and a health care provider should give the patient information so that they can make an informed decision as to whether the risk is worth taking.

42. The PCF has argued these consolidated cases are not subject to the MMA because the procurement of MPA was more similar to cases asserting premises liability or product liability claims.

43. This case is neither a premises liability case nor a products liability case nor has any other relationship-based duty been alleged outside of professional medical care. In the submission of the "Proposed Findings of Fact and Conclusions of Law," submitted by the PCF on September 28, 2015, the PCF has cited in paragraphs 12 and 17, Methodist Hosp. of Indiana,

Inc. v. Ray, 551 N.E.2d 463 (Ind. Ct. Appt. 1990). The Methodist Hosp. case involved Legionnaire's Disease at Methodist Hospital in Indianapolis. The court of appeals determined that the Legionnaire's Disease was not related to medical care and could have occurred at any large facility and, therefore, was not within the scope of the Indiana MMA. However, footnote 3 at page 466 of the Methodist Hosp. case is important to consider. Premises liability cases that are unrelated to medical care are not within the MMA. In footnote 3, the Court of Appeals distinguishes a case entitled Cashio v. Baton Rouge General Hospital and the footnote reads as follows:

> Defendant directs our attention to caselaw from other jurisdictions with malpractice legislation similar to ours, citing Cashio v. Baton Rouge General Hospital (1979) 1st Cir., La.App., 378 So.2d 182, as particularly persuasive. There, plaintiffs sued for damages where a patient died as a result of "hospital staph" infection acquired during surgery. Plaintiffs contended that the facts alleged were encompassed by the duty owed by a premises owner. The appellate court disagreed, determining that one of the obligations of a hospital to a patient was to provide clean and sterile facilities and that a claim alleging infection by "hospital staph" was within the conduct classified by the Louisiana Medical Malpractice Act. The court acknowledged that a hospital might be liable as a premises owner in "situations outside of malpractice, such as in slip-and-fall and similar tort cases." Id. at 185. Cashio is not dispositive of the issues raised here. The complaint alleged a failure of appropriate care during surgery and further characterized the patient's death as resulting from "hospital" staph. In contrast, Ray alleges negligent maintenance in a situation not necessarily unique to hospitals.

44. In this footnote the Louisiana case appears similar to the case at bar. The "hospital staph" infection was contracted by a patient during a surgical procedure, according to the allegations in that complaint, and it was determined to be covered by the medical malpractice act in Louisiana. Similarly, the infectious agents, as alleged by the plaintiffs, were allegedly contracted during the injection procedure by Dr. Park. This is not premises liability in Louisiana and it should not be premises liability in Indiana.

45. With respect to the claim that MPA is a product and not subject to the MMA, the small quantity of solution used in each injection of medical compound was incidental to the medical procedure of injection.

> The term "product" means "any item or good that is personalty at the time it is conveyed by the seller to another party. It does not apply to a transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product." I.C. 33-1-1.5-2.

St. Mary Medical Center, Inc. v. Casko, 639 N.E.2d 312 (Ind. App. 1994)

46. An ALR article has addressed a similar situation where tainted blood transfusions were given to patients and the Appellate Court of the State of Maryland held that the patients' claim against the health care provider for injuries allegedly flowing from a tainted blood transfusion was subject to Maryland's medical malpractice act, because it constituted medical services rather than a sale of a good:

> What patient claims against doctor, hospital, or similar health care provider are not subject to statutes specifically governing actions and damages for medical malpractice. 89 A.L.R.4th 887
>
> [24a] Blood transfusion
>
> The court in the case below held that a patient's claim against a health care provider for injuries allegedly flowing from a blood transfusion was subject to a statute expressly governing medical malpractice actions because such activities constituted medical services, rather than the sale of a good.
>
> Finding that a blood transfusion constituted the provision of a service, rather than the sale of a product, the court in Roberts v Suburban Hospital Asso. (1987) 73 Md App 1, 532 A2d 1081, CCH Prod Liab Rep P 11583, 4 UCCRS2d 1410, held that a hemophiliac's negligence claim against a hospital, arising out of the transfusion of contaminated blood, was subject to the Health Claims Arbitration Act. Due to the patient's hemophilia, he required regular transfusions of blood. In 1985, he was diagnosed as having acquired AIDS through transfusion of contaminated blood and instituted a suit against the hospital based on three theories: negligence, strict liability, and breach of the implied warranties of merchantability and fitness. Reviewing the case law, the court found that claims such as premises liability, slander, and assault, arising from a professional's failure to exercise due care in a nonprofessional situation, were not within the

scope of the act, but noted that where such claims were related to, and incorporated, a negligence claim which was arbitrable under the act, they too were subject to arbitration. Finding that the patient's negligence claim would have been subject to arbitration because it arose from the rendering or failure to render health care, the court concluded that if the negligence count had not been dismissed, the strict liability and breach of warranty would also have been subject to arbitration since they were related to the negligence count, which incorporated their allegations by reference. Turning to consideration of whether the strict liability and breach-of-implied-warranty claims were independently subject to arbitration, the court stated that the applicability of the act depended on whether a blood transfusion constituted the provision of health care services or the sale of a product. Concluding that implied warranties of merchantability and fitness were applicable only to the sale of "goods" and the doctrine of strict liability was applicable only to the sale of "products," the court found that neither theory was applicable to a transaction predominantly concerned with the provision of services. Noting that a statute limiting the liability of those who process or otherwise handle blood was recently amended to provide that any such person was performing a service and not subject to strict liability in tort, or to the implied warranties of merchantability and fitness, the court stated that although the preamendment statute was not determinative of this case, since it applied only to hepatitis contamination, it would be anomalous to determine what theories of recovery were available based on a type of infection contracted. Reviewing the law of other jurisdictions, the court found that where a patient bargained for, and the hospital agreed to make available, human skill and medical science to restore the patient's health, the contract was one for services, and because a blood transfusion involved medical skill, it would be artificial to conclude that the product predominated over the service and to draw distinctions based on whether the patient had received only a transfusion or had received some other service from the hospital as well.

47. The PCF is also arguing that ruling in favor of the plaintiffs' and SBC's position that this is covered by the Medical Malpractice Act would greatly expand liability for all products used by doctors and hospitals, but such is not at risk.

CONCLUSIONS

48. The specific issue is whether the act of selecting a medical compounding company to procure patient-specific medical compounds pursuant to a prescription that should have been delivered directly to the compounding company required due diligence by the medical staff of

the clinic to determine the safety of that facility. Under that very limited view, these acts of selection and procurement are acts of health care as defined by and covered by the Medical Malpractice Act, and not general negligence. Again, it is important to distinguish a compounding company from FDA regulated pharmaceutical manufacturers, and specifically the difference between writing a prescription from a doctor to a pharmacy, which is a dispensing retail warehouse, versus writing a prescription to a compounding company where the product is actually created. This is a very significant difference.

49. This decision should not be read by any plaintiff or other litigant that this court views the PCF as an insurer of all medical and non-medical products used in hospitals and clinics. Certainly, that is not the case. However, when a patient-specific prescription is required and a doctor chooses to use preservative-free medicine that is to be injected into the spinal area of a patient, that doctor and clinic has a due diligence obligation to use careful medical judgment in selecting a safe source for the medicine.

50. For purposes of this Motion to Dismiss, procurement by the SBC of MPA by a prescription from a clinic doctor for a compound from a pharmacy to obtain a preservative-free solution to be injected into the spine of a specific patient is "professional services" as used in I.C. 34-18-2-18. It is for the Medical Review Panel to decide whether any standard of care was breached by the SBC. Because plaintiffs' claims are governed by the MMA, the Court lacks subject matter jurisdiction to hear the complaints until after a medical review panel opinion has been issued. Howard Regional Health System v. Gordon, 952 N.E.2d 182, 186 (Ind. 2011). The opposition to this motion by the PCF has been carefully considered and any ramifications as to the solvency of the fund should be addressed to Department of Insurance to consider under the

statutory scheme for assessing medical providers in determining contributions to the fund, and, if necessary, the legislature.

THEREFORE, the consolidated Motion to Dismiss of SBC is granted in part:

1. All proceedings in this court are stayed until compliance with all proceedings before the medical review panels,

2. The plaintiffs are granted thirty (30) days to amend their complaints to show anonymous defendants, or their complaints will be dismissed.

3. The exceptions to the amendment requirement are the cases involving Terri Rethlake v. ABC Clinic, Cause No. 71D06-1405-CT-000136 and John Reed, et al v. ABC Clinic, Cause No. 71D06-1408-CT-000300. These parties are granted leave to submit a stipulation as to the applicability of this ruling to those cases which have been filed with anonymous defendants.

4. A status conference is set for October 28, 2015 at 2:00 p.m. Attorneys may appear by a telephone conference call or in person.

DATED: OCT 1 2 2015

David C. Chapleau

DAVID C. CHAPLEAU
JUDGE, ST. JOSEPH SUPERIOR COURT